

REMARKS

Claims 1 and 17-19 have been amended to affirmatively recite, amongst other things, that the active ingredient is acetaminophen, and wherein the acetaminophen is released from the swallowable immediate release tablet by 30 minutes in pH 5.8 buffer. Claims 17-19 were also amended to provide consistency in referring to the tablet. Support for this amendment can be found throughout the specification at, for example, Examples 1 to 4.

It is submitted that no new matter has been added by the above amendments.

Claims 2 and 20 have been cancelled without prejudice, reserving full rights to re-introduce the subject matter of such claims in the present application or in a future application claiming the benefit of priority to the present application.

Claims 1, 3-15, and 17-19 are currently pending in the present application.

Obviousness Rejections

Claims 1-15 and 17-20 were rejected under 35 USC §103(a) as being unpatentable over by Cheng, US Patent No. 6,099,859 (“Cheng”), or Smith, US Patent No. 6,194,000 (“Smith”), or Harbit, US Patent No. 3,108,046 (“Harbit”) in view of Joshi, U.S. Patent No. 5,030,447 (“Joshi”) (Paper No. 20060530 at 2.)

For the reasons set forth below, the rejection, respectfully is traversed.

The disclosures of Cheng, Smith and Harbit set forth is previous papers submitted during prosecution of the present application are incorporated herein by reference.

Joshi discloses

The invention is particularly adapted to pharmaceutical compositions containing pravastatin as the medicament. Pravastatin, will be present in an amount within the range of from about 1 to about 60% and preferably from about 3 to about 50% by weight of the composition. 55

To ensure acceptable stability, the composition of the invention will include a basifying agent which will raise the pH of an aqueous dispersion of the composition to at least 9 and preferably to a pH of at least about 9.5. The basifying agent will be present in an amount within the range of from about 1 to about 75% by weight and preferably from about 2 to about 70% by weight of the composition. Examples of basifying agents which may be included herein include but are not limited to magnesium oxide, aluminum oxide, an alkali metal hydroxide 60

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such as sodium hydroxide, potassium hydroxide or lithium hydroxide or an alkaline earth metal hydroxide such as calcium hydroxide or magnesium hydroxide, with magnesium oxide being preferred.

5 The composition of the invention will also include one or more fillers or excipients in an amount within the range of from about 5 to about 90% by weight and preferably from about 10 to about 80% by weight such as lactose, sugar, corn starch, modified corn starch,
10 mannitol, sorbitol, inorganic salts such as calcium carbonate and/or cellulose derivatives such as wood cellulose and microcrystalline cellulose.

One or more binders will be present in addition to or in lieu of the fillers in an amount within the range of
15 from about 5 to about 35% and preferably from about 10 to about 30% by weight of the composition. Examples of such binders which are suitable for use herein include polyvinylpyrrolidone (molecular weight ranging from about 5000 to about 80,000 and preferably
20 about 40,000), lactose, starches such as corn starch, modified corn starch, sugars, gum acacia and the like as well as a wax binder in finely powdered form (less than 500 microns) such as carnauba wax, paraffin, spermaceti, polyethylenes or microcrystalline wax.

In making the rejection as to Cheng, the Examiner asserted that

Cheng teaches a controlled release oral tablet comprising from 75-95% drug and up to about 40% waxes (see column 3, lines 34-49; and column 5, lines 30-36). The tablet provides both, immediate release and controlled release (see column 5, lines 22-26). The tablet further comprises fatty acid, surfactant (flow aid), and chelating agent (column 3, lines 51-60), and can further be coated with a semi-permeable membrane

comprises cellulose derivatives polymer (see column 4, lines 11-44). Cheng also discloses the tablet is prepared by compression (see column 6, lines 35-41). (Paper No. 20060530 at 2-3.)

As to Smith, the Examiner further asserted that

Smith teaches an analgesic composition comprising immediate and controlled release forms (see abstract). The immediate release comprises up to 90% of the analgesic agent, polyethylene glycol, waxes, and other carriers (column 2, lines 39-50; and column 3, lines 29-51). The dosage form provides from about 1-5000 mg/day of the analgesic agent (ID). The composition is in for oral administration in tablet or capsule or granule form (column 2, lines 55-67). Suitable coating to provide sustained release comprises cellulose derivatives polymer (column 4, lines 26-45).

(*Id.* at 3.)

As to Harbit, the Examiner asserted that:

Harbit teaches a high dose tablet comprising from about 75% to about 98% drug and wax, such as paraffin wax or shellac wax (column 3, lines 1-31). The tablet dosage further comprises lubricant (column 4, lines 9-19). The dosage form provides both immediate release and sustained release (column 4, lines 21-31).

(*Id.* at 3.)

The Examiner acknowledged, however, that the cited documents do not explicitly teach wax in powder form.. (*Id.* at 3.)

To fill the acknowledged gap, the Examiner relied upon Joshi for “teach[ing] a tablet dosage form comprising wax in finely powered form having size less than 500 microns such as microcrystalline wax, carnauba wax, or paraffin.” (*Id.*) The Examiner concluded:

22-24). Thus, it would have been obvious to one of ordinary skill in the art to modify the wax in the tablet dosage of Cheng, Smith or Harbit using the finely powdered wax in view of the teaching of Joshi, because Joshi teaches a composition include one or more powder wax result in an excellent storage stable even though it includes a medicament which may degrade in a low pH environment (column 1, lines 37-40), because Cheng, Smith or Harbit teaches the use of wax in tablet dosage form comprising active agents. (*Id.*)

As admitted by the Examiner: Cheng discloses a “controlled release” tablet, Smith discloses a composition having an immediate release form and a sustained release form, and Harbit discloses a sustained release tablet. None of Cheng, Smith, or Harbit discloses a dosage form that provides both immediate release and sustained release. It is not seen where any of these cited documents disclose or suggest tablets that are immediate release tablets. They are either controlled release, sustained release or a combination of immediate release and sustained release. It is not seen where Joshi would close this gap.

Binding precedent is clear that the “[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.” ATD Corp. v. Lydall, Inc., 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. See Ruiz v. A.B. Chance Co., 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed. Cir. 2000); ATD Corp., 159 F.3d at 546, 48 USPQ2d at 1329; Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc., 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) (“When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.”).

It appears that the Examiner has culled facts from disparate documents in an attempt to make a *prima facie* case of obviousness. However, a *prima facie* case of

obviousness cannot ignore the fundamental aspect of the invention, viz., a swallowable immediate release tablet. It is submitted that none of the documents relied on by the Examiner appear to be direct to immediate release compositions. For this reason, the rejection is improper and should be withdrawn.

Further, as to the current amendments, it is not seen where any of the documents disclose or suggest acetaminophen as an ingredient or the fact that the acetaminophen is released from the swallowable immediate release tablet by 30 minutes in pH 5.8 buffer. For this additional reason, the rejection is improper and should be removed.

Finally, to the extent claims 2 and 20 stand rejected, it is submitted that this rejection is moot in view of the cancellation of these claims without prejudice.

Claims 1-15 and 17-20 were rejected under 35 USC §103(a) as being unpatentable over by Cheng or Smith, or Harbit, in view of Remon, WO 01/21155, ("Remon") and Mueller, U.S. Patent No. 5,643,984 ("Mueller") (Paper No. 20060530 at 4.)

For the reasons set forth below, the rejection, respectfully is traversed.

The disclosures of Cheng, Smith, Harbit and Remon set forth in previous papers submitted during prosecution of the present application are incorporated herein by reference.

Remon additionally discloses

As is readily apparent, the solid shaped articles of the present invention provide numerous advantages over the prior art when used for the biological treatment of mammals and plants such as mentioned in the above methods of treatment. They are able to provide a formulation which disintegrates rapidly in water to form an instantaneous
20 homogenous suspension of adequate viscosity to be swallowed without premature release from controlled-release particles while providing a ready measured dose, even for the administration of large dosages. When using a viscosity enhancer, the solid shaped article of the present invention are useful for preparing an immediate release suspension (when no coating polymer is provided on the biologically active ingredient-loaded beads or
25 when no polymer is incorporated into the matrix system of the biologically active ingredient-loaded beads) or a sustained release suspension (when such a polymer is coated onto or incorporated into the biologically active ingredient-loaded beads), and rapid disintegration occurs when the solid shaped article of the present invention is immersed in water or an aqueous solution. Disintegration occurs within a couple of
30 seconds and give rise to the *in situ* formation of a suspension over a period of less than 1 minute. The *in situ* suspension is useful for preparing sustained release liquid products namely for young children and elderly patients who cannot swallow tablets or capsules, or for patients who require large doses of biologically active ingredients, where

swallowing large dosage forms is difficult.

(p. 24 ln. 16 – p. 25, ln.1.)

Mueller discloses

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ABSTRACT

A new wax composition for use in the ink industry, which composition is prepared from: (a) 40% to 90% of solvent having a boiling point within the range of about 100° to 550° C., said solvent being selected from the group consisting of aromatic and aliphatic solvents, (b) 10% to 40% of wax having an average particle size within the range of about 1 to about 300 microns, (c) 5% to 40% of polymeric pour point depressant, and optionally dependant on the characteristics required, 4% to 40% of a resin material which is soluble in aromatic and aliphatic solvents.

In making the rejection, the Examiner stated:

Cheng, Smith or Harbit is relied upon for the reason stated above. The references do not explicitly teach wax in powder form. Remon discloses a rapidly disintegrating tablet comprising an active agent and wax (page 10, lines 14-18; page 19, lines 10-21). Wax includes microcrystalline wax or a natural wax (page 11, line 7 through page 15, line 8). The composition further contains disintegrants, swellable materials as well as other fillers (page 15, line 9 - page 18, line 6). Active agents are chosen from a wide variety of known pharmaceutical agents (page 19, line 22 - page 20, line 18). The composition also includes a film coating (page 21, line 4 - page 22, line 8). The tablets are produced by compression (page 23, lines 3-9). The tablets are rapid disintegration tablets (page 24, line 16 - page 25, line 1).

Remon does not expressly teach the particle size of the microcrystalline wax. Mueller teaches typical microcrystalline hydrocarbon waxes having particle size within the range of about 1 μm to about 300 μm (column 2, lines 55-65). Thus, it would have been obvious for one of ordinary skill in the art to use microcrystalline wax in view of the teachings of Remon and Mueller for the composition taught by Cheng, Smith or Harbit, because Remon teaches the use of wax in tablet dosage form that disintegrate rapidly in water (page 9, lines 5-10), because Cheng, Smith or Harbit teaches the use of wax in tablet dosage form, and because Mueller teaches microcrystalline wax having particle size within the claimed range is known and typical.

(Paper No. 20060530 at 4.)

As admitted by the Examiner, Cheng discloses a “controlled release” tablet, Smith discloses a composition having an immediate release form and a sustained release form, and Harbit discloses a sustained release tablet. None of Cheng, Smith, or Harbit discloses a dosage form that provides both immediate release. The Examiner then relied on Remon for disclosing, among other things, a rapidly disintegrating tablet. However, it is not seen where Remon disclose or even suggests the desirability of a swallowable

immediate release tablet. In fact, it is respectfully submitted that Remon teaches away from a **swallowable** tablet, including an immediate release swallowable tablet.

It is well established that a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant. *In re Gurley*, 27 F.3d 551, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994).

Remon specifically recites “the solid shaped articles of the present inventionprovide[s] a formulation which distintegrates rapidly in water to form an instantaneous suspension of adequate viscosity to be swallowed without premature releast from controlled release particles....or an immediate release suspension...[which] is useful ... for young children and elderly patients **who cannot swallow tablets or capsules**, or for patients who require large doses of biologically active ingredients, where swallowing large dosage forms is difficult.” Remon at 24-25. Thus, it is not seen where any tablet produced by Remon would be a swallowable immediate release tablet per se, much less a swallowable immediate release tablet useful in obtaining the result sought by the present invention. Thus, to the extent the rejection relies on Remon, it is submitted that Remon teaches away from the present invention and the rejection is improper and should be withdrawn.

Additionally, “{when a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. . . . Stated another way, the prior art as a whole must suggest the desirability of the combination. . . . The source of the teaching, suggestion, or motivation may be the nature of the problem, the teachings of the pertinent references, or the ordinary knowledge of those skilled in the art.” *In re Fulton*, 391 F.3d 1195, 73 USPQ 2d 1141, 1145 (Fed. Cir. 2004) (quotations omitted). It is noted that the Examiner relied on Mueller for the particle size of wax. It is not seen where in this record one of ordinary skill in this art would look to the disclosure of **ink compositions** to find motivation in selecting the particle size of wax to be used in a **swallowable immediate release tablet**. To the extent the rejection relies on Mueller, it is improper and should be withdrawn.

Binding precedent is clear that the “[d]etermination of obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to

fit the parameters of the patented invention.” *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, 546, 48 USPQ2d 1321, 1329 (Fed. Cir. 1998). There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor. *See Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 665, 57 USPQ2d 1161, 1167 (Fed. Cir. 2000); *ATD Corp.*, 159 F.3d at 546, 48 USPQ2d at 1329; *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 1072, 30 USPQ2d 1377, 1379 (Fed. Cir. 1994) (“When the patented invention is made by combining known components to achieve a new system, the prior art must provide a suggestion or motivation to make such a combination.”).

It appears that the Examiner has culled facts from disparate documents in an attempt to make a *prima facie* case of obviousness. However, a *prima facie* case of obviousness cannot ignore the fundamental aspect of the invention, viz., a swallowable immediate release tablet. It is submitted that none of the documents relied on by the Examiner appear to be directed to swallowable immediate release tablets. For this reason, the rejection is improper and should be withdrawn.

Further, as to the current amendments, it is not seen where any of the documents disclose or suggest acetaminophen as an ingredient or the fact that the acetaminophen is released from the swallowable immediate release tablet by 30 minutes in pH 5.8 buffer. For this additional reason, the rejection is improper and should be removed.

To the extent claims 2 and 20 stand rejected, it is submitted that this rejection is moot in view of the cancellation of these claims without prejudice.

Finally, the Examiner is invited to call the applicants’ undersigned representative if any further action will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response. In fact, if the claims of the application are not believed to be in full condition for allowance, for any reason, the applicants respectfully request the constructive assistance and suggestions of the Examiner in drafting one or more acceptable claims pursuant to MPEP §707.07(j) or in making constructive suggestions pursuant to MPEP §706.03 so that the

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application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Respectfully submitted,

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